NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SCHERING CORPORATION and MSP SINGAPORE COMPANY LCC, Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA and GLENMARK PHARMACEUTICALS LTD., Defendants.	CIVIL ACTION NO. 07-1334 (JLL) **OPINION**

LINARES, District Judge.

This matter is before the Court by way of an application for claims construction by Plaintiffs Schering Corporation ("Schering Corp.") and MSP Singapore Company LLC (collectively with "Schering Corp.," "Plaintiffs" or "Schering") and Defendants Glenmark Pharmaceuticals Inc., USA and Glenmark Pharmaceuticals Ltd. ("Defendants" or collectively, "Glenmark"). The parties seek the Court's interpretation of certain language contained in the independent claims of United States Patent No. 37,721 (the "'721 patent"), specifically terms in claims 9 and 13.[1] The Court held a Markman hearing on July 29, 2008,[2] and has considered the parties' written and oral arguments. The Court sets forth herein its construction of the disputed claim terms.

[1] At oral argument, the parties conceded that there is an agreement on the terms of claims 8 and 12.

[2] "Tr." refers to the transcript of the July 29, 2008 Markman hearing.

I. Factual and Procedural History

This patent infringement case involves the '721 patent, a patent for the hydroxyl-substituted azetidinones compound ezetimibe, marketed and sold commercially as the drug Zetia. Schering Corp. is the holder of the '721 patent; MSP Singapore Company LLC is the exclusive licensee for Zetia. Ezetimibe is a hypocholesterolemic agent used in the treatment of atherosclerosis. In non-scientific terms, Zetia is used to reduce cholesterol. Importantly, ezetimibe accomplishes its end differently than previous drugs: it blocks the absorption of cholesterol from a person's diet. According to Schering, ezetimibe is the first and only cholesterol absorption inhibitor approved by the U.S. Food and Drug Administration ("FDA") and available on the open market.

Plaintiffs first filed the '721 patent on September 21, 1993. The United States Patent and Trademark Office ("PTO") issued the original patent in 1998 as U.S. Patent No. 5,767,225, and thereafter reissued it as the '721 patent on May 28, 2002. The FDA approved ezetimibe on October 25, 2002. The patent contains three different types of claims: claims to (1) compounds (claims 1, 10, 11), (2) pharmaceutical compositions (claims 8, 12), and (3) methods of treating atherosclerosis using ezetimibe (claims 9, 13). On October 25, 2006, Glenmark Ltd. filed an abbreviated new drug application ("ANDA") with the FDA, seeking to market a generic version of Zetia along with a Paragraph IV certification alleging that the '721 patent is invalid or will not be infringed by the sale of a generic copy of Zetia.

Plaintiffs initiated this action on March 22, 2007, claiming that Glenmark infringed claims 3 and 8-13 of the '721 patent. On June 7, 2007, Defendants answered the complaint, asserting various affirmative defenses and bringing counterclaims against Schering. Glenmark

filed an amended answer and counterclaim on March 10, 2008, seeking a declaratory judgment finding that both the '721 patent and the patent term extension for the '721 patent are invalid and unenforceable.[3]

Pursuant to the Pretrial Scheduling Order entered by this Court on November 19, 2007. The Scheduling Order set a November 30, 2007 meet and confer among the parties regarding claim construction. At said meeting, the parties were able to agree on construction of all but two of the claim terms. The parties then filed their respective opening claim construction briefs on January 14, 2008, and the corresponding oppositions on February 12, 2008.

The disputed language of the '721 patent consists of two separate terms in claims 9 and 13. The first is the term "administering" and the second, "in need of such treatment."[4] Claims 9 and 13 read as follows:

> 9. A method of treating or preventing atherosclerosis or reducing plasma cholesterol levels comprising administering to a mammal in need of such treatment an effective amount of a compound of claim 1.
>
> 13. A method of treating or preventing atherosclerosis or reducing plasma cholesterol levels comprising administering to a mammal in need of such treatment an effective amount of a compound according to claims 10 or 11.

II. Legal Standard

A court's analysis of a patent infringement claim is two-fold. Tate Access Floors, Inc. v.

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[3] While Plaintiffs assert infringement of only seven claims, all thirteen claims of the '721 patent are implicated in this litigation as Glenmark counterclaimed based on the invalidity and unenforceability of the patent as a whole.

[4] In their briefing, the parties disputed the meaning of the preamble of claims 9 and 13, i.e., "A method of treating or preventing atherosclerosis or reducing plasma cholesterol levels," with respect to giving antecedent meaning to "in need of such treatment." Because the parties' argument at the Markman hearing and their post-argument briefing focused on the meaning of "in need of such treatment," the Court will construe said phrase rather than the preamble.

Interface Architectural Resources, Inc., 279 F.3d 1357, 1365 (Fed. Cir. 2002). The court must first define the meaning and scope of the patent claims as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The court then engages in a comparison of the claims as construed to the alleged infringing product (or method). Tate, 279 F.3d at 1365. At this stage, the Court must only engage in the first step.[5]

Claim construction is a matter of law to be determined solely by the court. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005), cert. denied, 546 U.S. 1170 (2006). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Id. at 1312 (quotations omitted). In construing the terms of a patent, a court should look first to the language of the claim itself. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The terms in the claim "are generally given their ordinary and customary meaning." Id. at 1582.[6] "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent

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[5] The parties have agreed that claims 3 and 8-13 of the '721 patent are infringed. (Tr. at 13:22-13:23; see also Civil Action No. 07-1334, CM/ECF docket no. 88, ¶ 5.) The Court need not address the issue of infringement until a later stage in the litigation.

[6] The Court recognizes that two situations exist in which it must enter a definition different from the ordinary and customary meaning: (1) where the "patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term," Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999) (citing In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994)), and (2) where "the term or terms chosen by the patentee so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used," id. (citing Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1554 (Fed. Cir. 1997)). Neither of these situations apply to the case at bar.

application." Phillips, 415 F.3d at 1313. A court "must look at the ordinary meaning in the context of the written description and the prosecution history." Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005). The court should turn to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004).

To this end, the court should first examine the intrinsic record – the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Vitronics, 90 F.3d at 1582 (citing Markman, 52 F.3d at 979). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. Indeed, the Federal Circuit explains that the specification is "'usually . . . dispositive . . . [and] the single best guide the meaning of a disputed term.'" Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317. The specification is also an important guide in claims construction as it may contain "an intentional disclaimer, or disavowal, of claim scope by the inventor." Id. at 1316.

Additionally, the court should consult the patent's prosecution history as it "provides evidence of how the PTO and the inventor understood the patent." Id. Courts should be circumspect in reviewing a prosecution history as it represents "an ongoing negotiation between the PTO and the applicant, rather than the final product of the negotiation . . . ." Id.

A district court may also examine extrinsic evidence – "all evidence external to the patent and prosecution history." Markman, 52 F.3d at 980; Phillips, 415 F.3d at 1317-18 (stating that

the Federal Circuit "ha[s] authorized district courts to rely on extrinsic evidence"). Such evidence consists of testimony by the inventor or by experts, dictionaries, and treatises. Markman, 52 F.3d at 980. In particular, a court may find reference to technical dictionaries useful "in determining the meaning of particular terminology." See Phillips, 415 F.3d at 1318. However, extrinsic evidence is generally thought less reliable than the patent and prosecution history, id. at 1318-19; in essence, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language," C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quotation omitted). With this framework in mind, the Court now turns to the disputed claim language.

III. Discussion

A. "Administering"

The Court will briefly outline the parties' respective positions prior to undertaking its own analysis of the construction of "administering." Plaintiffs propose that the Court construe "administering" to mean "providing a compound according to claims [1, 10 or 11] in a conventional dosage form." In simple terms, Plaintiffs state that "administering [in] its normal common sense term . . . is ingesting." (Tr. at 27:18-27:19.) Defendants contemplate that the same means to "give as a remedy," and that to provide such remedy includes the ingestion of a prodrug where the compound forms *in vivo*. Defendants' proposed construction includes the administration of the metabolite that forms in the body after a patient ingests ezetimibe. Defendants argue that "[w]hat matters is whether the drug gets to the body where it is needed"–in essence, that "administering" has nothing to do with "ingesting." (See id. at 75:5-75:9.)

As an initial matter, the Court must define the terms "prodrug" and "metabolite" as both

are relevant to the proposed constructions of "administering." A "prodrug" is a "drug which makes an inner body transformation," Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 939 n.4 (Fed. Cir. 1992), or, as the parties agree, "the chemical in the drug that is given in the first instance." (Tr. at 20:6-20:8; see id. at 50:18-50:19.) Dorland's Illustrated Medical Dictionary defines "prodrug" as "a compound that, on administration, must undergo chemical conversion by metabolic processes before becoming an active pharmacological agent; a precursor of a drug." Dorland's Illustrated Medical Dictionary 1513 (2003). With respect to the latter term, in Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373 (Fed. Cir. 2003), the Federal Circuit defined a metabolite as, "the compound formed in the patient's body upon ingestion of a pharmaceutical. The ingested pharmaceutical undergoes a chemical conversion in the body to form a new metabolite compound." Id. at 1375. The definitions of "prodrug" and "metabolite" are relevant here inasmuch as Plaintiffs contend that "administering" does not include administering a prodrug that forms a metabolite *in vivo* while Defendants propose that it in fact does.

The Court begins its claim construction of "administering" by examining the claim language and "presume[s] that the terms in the claim mean what they say." Johnson Worldwide Assocs. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999). The claim itself does not contain an explicit definition of "administering." In the absence of a clearly defined meaning of said term in the claim language, the Court looks to the ordinary and customary meaning of the term. Id. at 990. The Court turns to the patent specification for guidance here. See Vitronics, 90 F.3d at 1582.

The patent specification does not expressly define "administered," but, as Schering

suggests, defines the term by implication. "Administering" is used primarily in conjunction with the term "dose" or "dosage" throughout the specification. Such use suggests that "administered" applies only to those compounds given to a patient externally, not those that contemplate the *in vivo* formation of metabolites with respect to the recited compounds. The definition of the patented invention states that it is "related to a pharmaceutical composition comprising a compound of formula I and a pharmaceutically acceptable carrier. Compounds of formula I can be administered in any conventional dosage form . . . ." (Id. at col. 21:16-21:19 (emphasis added).) Further examples of the referred-to usage are: "The present invention also relates to a pharmaceutical composition comprising a compound of formula I . . . [that] can be administered in any conventional dosage form," (id. at col. 21:16-21:21 (emphasis added)), and, "The exact dose of any component of the combination to be administered is determined by the attending clinician and is dependent on the potency of the compound administered . . ." (id. at col. 21:49-21:52 (emphasis added)).

Importantly, the patent provides specific examples of "oral dosage forms": "capsule, tablet, power cachet, suspension or solution." (Id. at col. 21:19-21:21.) The Court understands these dosage forms to be of the sort that are administered externally, particularly in light of the fact that the patent does not make any reference of the applicability of said forms to metabolites.

To further support the Court's understanding of "dose" and "dosage form" in reference to the disputed term, the patent specification provides specific dosage amounts for different body weights. The specification provides that "[t]he exact dose to be administered is determined by the attending clinician and is dependent on the potency of the compound administered . . . ." (Id. at col. 21:50-21:53.) The specification also states that a particular amount of the compound – a

"dose" – should be given "1 to 2 times a day" and then provides the aggregate number of milligrams to be provided to a patient who is "administered" the dose twice daily. (See id. at col. 21:45-21:50.)

The Court finds In re Buspirone Patent Litig., 185 F. Supp. 2d 340 (S.D.N.Y. 2002), instructive on the use of "dose" in this context. There, the district court recognized that the ordinary meaning of "dose" "has clear meaning in reference to an externally-measured amount of a substance that is to be ingested or administered into the body all at once, but would have no precise meaning if used to refer to *in vivo* levels . . . ." Id. at 353 (emphasis added). The Buspirone Court held that the claim to be construed referred to the "administration of an externally-measured quantity of the metabolite into the body, and not the administration of a dose of buspirone into the body, which, in turn, produces variable and changing levels (not doses) of the metabolite in the bloodstream." Id. (emphasis in original).[7]

The use of "administering" with "dose" or "dosage form" – along with the Buspirone Court's holding – suggests to the Court that the term "administering" contains a preingestion limitation. There is no discussion of how many times the compound forms *in vivo* each time it is given in a dosage form such that the reference to the number of times a day would have any meaning if the term "administering" were to bear the meaning attributed to it by Defendants. The patent does not reference a "dose" or "dosage form" that corresponds to a metabolite or a compound formed *in vivo* nor does it provide any information with respect to how to determine

[7] The Court is mindful that Buspirone may be distinguished on the basis that the patent-holder there was claiming the metabolite in a dose form and specifically used the word "dose" in the claim itself. However, the examination of the term there is useful in that the patent specification here uses administering in conjunction with "dose" or "dosage form."

the amount of the compound to be administered when said compound is formed *in vivo*. (See Tr. at 37:23-38:14.)[8]

Defendants argue that because the claims do not use the "magic words"– "pharmaceutically acceptable carrier" or "dose" – to claim only the "pill that somebody swallows" exclusive of the metabolite, "administering" does not bear a preingestion limitation. (See Tr. at 49:22-50:2.) Schering stressed at the Markman hearing that the claims need not contain words of limitation like "dose" or "pharmaceutically acceptable carrier" if drafted as a method of administering claim in the vein of the example set out in Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373 (Fed. Cir. 2003) (hereinafter "Geneva"), discussed infra. (Tr. at 83:13-84:15.) Moreover, the language of claims 9 and 13 refers to "administering" an "effective amount" of the compound.[9]

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[8] At oral argument, Plaintiffs urged that the definition of "prodrug" actually undercuts Defendants' argument that the ordinary meaning of "administering" is used in reference to a "prodrug." The Dorland's Illustrated Medical Dictionary definition of "prodrug" – "a compound that, on administration, must undergo chemical conversion by metabolic processes before becoming an active pharmacological agent; a precursor of a drug" – suggests that administration happens prior to the formation of the metabolite *in vivo*.

[9] Claim 9 specifically refers back to claim 1 in which Schering refers to the "compound" and "pharmaceutically acceptable salt." (See '721 patent, col. 37:35-37:48; id. at col. 40:1-40:4.) Defendants argue that the Federal Circuit's holding in Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418 (Fed. Cir. 1994), that the claim at issue there was "not limited to the compound in its pre-ingested form . . .," id. at 1422, indicates that the term "compound" "includes what happens to it in the body." (Tr. at 64:10-64:17.) Zenith does not stand for the broad proposition suggested by Defendants, but rather is specific to the claim at issue there in light of the detailed prosecution history. See Zenith, 19 F.3d at 1421-22. Thus, the Court will not defer to the Zenith holding in understanding the use of the word "compound" when examining its relevance in construing the term "administering" in the context of this case.

Moreover, Glenmark contradicts itself on this point. At oral argument, Glenmark stated that if Schering had used the "magic words" in the claims, "that would indicate it was in a pill form, that it is the compound being administered." (See Tr. at 55:18-55:23.) Glenmark's use of

In response to the Court's question at the Markman hearing about whether "effective amount" is equivalent to a "dosage," Glenmark stated that an effective amount is "an amount that once it gets into [the] body is sufficient to treat or prevent atherosclerosis or reduce plasma cholesterol. It's an effective amount to do what it says." (Id. at 55:3-55:11.) To illustrate the point, Glenmark explained that "a scientist is going to know if I give ten milligrams, and only 50 percent of it turns into the metabolite I need, an effective amount is five milligrams, and I have to give [the patient] ten." (Id. at 55:15-55:18.)

To debunk this point and urge the Court to find in favor of their proposed construction, Plaintiffs point the Court to the Federal Circuit's decision in Geneva. Geneva concerned the '233 and '716 patents held by Schering Corp. See generally Geneva, 339 F.3d 1373. The '233 patent was prior art to the '716 patent both of which covered the antihistamine loratadine, the active ingredient in Schering Corp.'s drug, Claritin. The later-in-time patent, the '716 patent, covered a metabolite of loratadine, "descarboethoxyloratadine," colloquially referred to as "DCL." Claims 1 and 3 of the '716 patent were compound claims covering DCL and its salts. While the '233 patent disclosed a class of compounds including loratadine, it did not expressly disclose DCL and did not refer to metabolites of loratadine. Id. at 1375-76.

Upon expiration of the '233 patent, various generic drug manufacturers filed ANDA applications with the FDA seeking to market generic versions of loratadine. When Schering received notice of the filings, it filed an infringement suit against Geneva and the other alleged

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the term "compound" in this context suggests that a "compound" is what is provided externally, not inclusive of what "happens to it in the body."

offenders. On the parties' cross-motions for summary judgment,[10] the district court determined that the '233 patent did not expressly disclose DCL, but that DCL was necessarily formed as a metabolite upon the processes described in the '233 patent. Id. at 1376. On this basis, the district court found that the '233 patent had anticipated the claims at issue in the '716 patent and thus, granted defendants' motion for summary judgment on invalidity. Id. Schering appealed and the Federal Circuit affirmed. In considering this "case of first impression," id. at 1378, the Federal Circuit examined the question of whether a court could find anticipation when the entire structure of the claimed subject matter is inherent in the prior art, and held that broad compound claims "are inherently anticipated by a prior art disclosure of a drug that metabolizes into the claimed compound," id. at 1380-81.

The Federal Circuit in Geneva stated that its holding did not "preclude patent protection for metabolites of known drugs," if the same were claimed properly. Id. at 1381. The court underscored that the metabolites could not receive patent protection via compound claims. Id. In *dicta*, however, the court stated that a "skilled drafter" would have the ability to write a claim to both (1) cover the metabolite and (2) avoid anticipation. The court provided examples of this type of claim, one of which was to "claim a method of administering the metabolite or the corresponding pharmaceutical composition." Id. Said example is relevant to the case at bar in that claims 9 and 13 are method claims regarding the administration of the pharmaceutical composition corresponding to ezetimibe. Plaintiffs argue that claims 9 and 13 of the '721 patent cover only administering the external compound of ezitimibe and not its corresponding

[10] Prior to the court's adjudication of the motions, all parties stipulated to a construction of claims 1 and 3 that covered DCL in all its forms, including "metabolized within the human body" and "synthetically produced in a purified and isolated form."

metabolites because the Federal Circuit made explicit that a patent holder may get a patent on a method of administering the metabolite even if the metabolite formed in the body in prior art.[11]

Defendants state that the Court should not credit the Federal Circuit's *dicta* in Geneva. Instead, Defendants urge the Court to defer to the decision in Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., et al., 348 F. Supp. 2d 713 (N. D. W.Va. 2004). In Ortho-McNeil, the district court considered the alleged infringement of the '407 patent, held by Johnson & Johnson, the parent company of Ortho-McNeil Pharmaceuticals, Inc. (hereinafter "Ortho-McNeil"). The '407 patent claimed the compound known as levofloxacin, an antibiotic that Ortho-McNeil markets and sells under the name "Levaquin," used to treat infections such as pneumonia and chronic bronchitis. The court construed, inter alia, claims 2 and 5 of the '407 patent, a compound claim covering levofloxacin and a method claim covering the administration of "an antimicrobially effective amount" of levofloxacin to a patient, respectively. Id. at 720.

Defendant Mylan Laboratories, Inc. ("Mylan") conceded infringement, but argued that the patent was invalid on various grounds, including prior invention, indefiniteness, inequitable conduct, obviousness, and inherent anticipation. Id. The court held a hearing on the inherent anticipation defense and received briefing from the parties in lieu of closing arguments. The court then issued an opinion in which it considered, inter alia, whether the language "administering . . . an antimocrobially effective amount" limited claim 5 of the '407 patent. See id. at 730.

The Ortho-McNeil Court held that "[w]hether levofloxacin formed as the claimed

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[11] Plaintiffs also argue that the way in which the claims were drafted also avoids Defendants' inherent anticipation defense. Such an argument may be addressed at the validity stage of these proceedings.

compound inside the body or outside the body, as long as it is given remedially as medicine, then levofloxacin has been administered. Thus, claim 5 does not contain a preingestion limitation." Id. (emphasis added). The court arrived at its holding by examining the phraseology of the term "administering to said patient an antimocrobially effective amount" as a whole. The district court found that said language "could be read to provide a quantity limitation." Id. In essence, the term limited the claim to levofloxacin "in quantities that are antimicrobially effective" Id.

In examining the term "administering," the district court found that in order to provide an antimicrobially effective amount, it did not matter if the amount was delivered from outside the body or produced *in vivo*. Using the Merriam Webster Medical Dictionary definition of the term "administer" – "to give remedially (as medicine)," the court found that the specific quantity used to provide the remedy could be given regardless of whether the compound formed inside or outside the body. Id.

Schering argues that this Court should not give weight to Ortho-McNeil for two reasons. First, Plaintiffs contend that the Ortho-McNeil Court's claim construction is incorrect because it was conducted pre-Phillips, an thus incorrectly weighted the extrinsic evidence it examined.[12] Second, Plaintiffs contest this Court's deference to Ortho-McNeil on the grounds that it is inconsistent with Geneva.

While the Court is not convinced of the correct construction of "administering" based solely on either of these cases, the Court looks to the Federal Circuit's *dicta* in Geneva. The

[12] In discussing how to examine a claim, the district court stated that "[d]ictionaries have become not only a permissible source, but also a significant source, in ascertaining claim meaning." Ortho-McNeil, 348 F. Supp. 2d at 722. Only after the use of dictionaries parsing the terms of the claim did the Ortho-McNeil Court state that it must look at the specification. Id.

Court understands the Geneva language relied upon by Plaintiffs to suggest two things. First, that because a "skilled drafter" could craft a claim to a "method of administering" an isolated form of the metabolite, he or she could also craft a claim to a "method of administering" the patented product in its pre-ingested form. Geneva, 339 F.3d at 1381. Second, to claim the "metabolite," a "skilled drafter" – one who no doubt would have the wisdom of the Geneva *dicta* at his or her disposal – would do so by explicitly claiming it "with a pharmaceutically acceptable carrier." Id. Schering does not make the latter claim in the '721 patent, suggesting to the Court that it did not intend to specifically claim the metabolite.

The parties also offer extrinsic evidence in support of their respective positions. In addition to the Merriam-Webster's Dictionary definition – "to give remedially (~ a dose of medicine)", both parties cite to the American Heritage College Dictionary definition of "administering" –"to apply as a remedy: administer a sedative." Defendants state that the Court should be guided by the fact that neither of the definitions offered provide a preingestion limitation. Plaintiffs point out that the examples provided in both dictionaries reference something that is provided externally, i.e., a "dose" or "sedative."

While Plaintiffs cite a variety of technical dictionaries, most persuasive to the Court is the use of "administering" in the Merck Manual. The Merck Manual, a technical dictionary to be sure, provides insight as to those of ordinary skill in the art understand said term. See Phillips, 415 F.3d at 1318 ("Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention").

The Merck Manual defines "pharmacokinetics" as "the study of the time course of a drug and its metabolites in the body following drug administration." Merck Manual 2430 (15th ed. 1987) (emphasis added); see also Tr. at 42:10-42:15. Such a definition makes clear that metabolites form only after a drug is "administered," i.e., ingested. The above-cited definitions and their concomitant examples – although not dispositive in their own right – further convince the Court that the term "administering" is limited to providing compounds or substances externally and does not include the metabolites that form inside the patient's body.

After careful consideration of the intrinsic evidence, importantly the patent specification, as well as guidance from the Federal Circuit and the extrinsic evidence, particularly the Merck Manual, the Court finds that the term "administering" in claims 9 and 13 of the '721 patent includes only administering the pharmaceutical compound ezetimibe and not the metabolite that forms *in vivo* upon administration. Consequently, the Court construes "administering" in the context of the '721 patent to mean "to provide externally by way of ingestion."

B. "In Need of Such Treatment"

The parties' respective constructions of "in need of such treatment" diverge on whether said term requires intent. Plaintiffs propose that the term "in need of such treatment" requires the recognition and intent by the "direct infringer"[13] to treat atherosclerosis. (See Tr. at 31:3-33:12.) Defendants submit that no such intent is necessary, and that the phrase refers to the "population that needs the treatment," i.e., "the universe of people who will be given the drug as opposed to

[13] "Direct infringement" is "[t]he act of making, using, selling, offering for sale, or importing into the United States, without the patentee's permission, a product that is covered by the claims of a valid patent." Black's Law Dictionary (8th ed. 2004). Here, the parties agree that the doctor prescribing the product is the "direct infringer." (See, e.g., Tr. at 32:1-32:2.)

[those who] require[] . . . it." (Tr. at 61:18; see id. at 77:22-77:23.)

Glenmark states that the definition of the term agreed upon by the parties at the November 30, 2007 meet and confer writes out any intent. (Defs. Letter at 1-2, August 7, 2008.) At the November meeting, the parties agreed that "in need of such treatment" means "one or more therapeutic effects of the type identified in the preamble are required or wanted." (See Defs. Br., Decl. of Agnes Antonia, Ex. A at 4.) Defendants argue that "'wanted' suggests intent, [while] the term ['required'] does not [and] [t]hus, by agreeing to the disjunctive 'or' rather than 'and' the definition includes situations where the treatment is required but not wanted (i.e., no intent)." (Defs. Letter at 2, August 7, 2008.)

In looking at the ordinary meaning of the phrase, the Court turns to the Federal Circuit's examination of the same issue in Jansen v. Rexall Sundown, Inc., 342 F.3d 1329 (Fed. Cir. 2003). The claim language at issue in Jansen is close to the language in claims 9 and 13: claim 4 of the '083 patent read, in pertinent part, "A method of treating or preventing macrocytic magalolastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B12 deficiency which comprises orally administering combined vitamin B12 and folic acid to a human in need thereof . . . ." Id. at 1330 (emphasis added). The proximity of the language makes "it . . . natural [for this Court] to interpret [the claim language here] . . . in the same way [as the Jansen Court]." Id. at 1333. In Jansen, the court found the infringer's state of mind relevant in construing "in need of such treatment," holding that said term included the infringer's intent to use the drug for its intended purpose. Id. at 1334.[14]

[14] In Jansen, the patient was the direct infringer since the product at issue was an over-the-counter drug that the patient administered to him or herself. Such a difference is irrelevant to construction here as both infringers are able to recognize the "need for such treatment."

Here, the Court finds that "in need of such treatment" in claims 9 and 13 has intent written into it. The agreed-upon usage only enhances the Court's finding of intent. The words "required" and "wanted" both intimate an intent to use the drug for the purpose it was intended. A doctor prescribing the product at issue may not only "require," but also "want" the "therapeutic effect" of "treating or preventing atherosclerosis or reducing plasma cholesterol levels." "Wanted" does not excise the intent requirement out of the phrase. The Court finds that the agreed-upon meaning is consistent with a construction of the term that understands the direct infringer to have an appreciation for the purpose of the drug and prescribe it in order to remedy the conditions it is meant to treat.

IV. Conclusion

For the aforementioned reasons, the Court construes the disputed claims of United States Patent No. 37,721 as follows: (1) the term "administering" as contained in claims 9 and 13 of the '721 patent is construed to mean "to provide externally by way of ingestion" and (2) the term "in need of such treatment" in claims 9 and 13 is construed to mean "one or more therapeutic effects of the type identified in the preamble are required or wanted," with an understanding that the direct infringer administered the patented product with the intent to treat or prevent atherosclerosis. An appropriate Order accompanies this Opinion.

Dated: September 15, 2008

/s/ Jose L. Linares
United States District Judge